510(K) Summary Of Safety And Effectiveness

Submitter:
Zimmer Spine, Inc.
7375 Bush Lake Rd.
Minneapolis, MN 55439

Establishment Registration Number:
1649384

Contact Personnel:
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Director Regulatory Affairs
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SEP 0 3 2013

Date:
2 August 2013

Trade Name:
Ardis® Interbody System

Common Name:
Spinal Intervertebral Body Fusion Device

Classification Name and Reference:
Ardis® Interbody System is classified as Class II (MAX), Spinal Intervertebral Body Fusion Device, 21 CFR § 21 CFR 888.3080.

Predicate Device:
Zimmer Spine Ardis® Spacer System (a.k.a. Ardis Interbody System), K073202 (1/30/08 & Add to file 11/17/11)

Device Description::
The Ardis® Interbody System is a device for interbody fusion of the anterior column of the spine. The Ardis implant may be used to replace the disc. These cages are hollow so that bone can grow through the device, fusing the adjacent bony surfaces.

The Ardis implant is a hollow device with texture on two opposing convex sides, and is offered in various lengths, widths and heights. Zimmer Spine designed Ardis to be placed through a posterior or transforaminal approach and to address vertebrae in the lumbosacral region of the spine. The system contains implants of various sizes to accommodate different patient anatomy, and instruments for site preparation, trialing and insertion and extraction. The device is crafted from (polyetheretherketone) PEEK-OPTIMA (ASTM F2026). As PEEK-OPTIMA is radiolucent, radiographic markers are included in the distal and proximal ends of the PEEK implants. The markers consist of tantalum wires and beads (ASTM F560) that are press fit into small holes in the implant. Additionally, the Zimmer Spine Ardis® Interbody System includes the instrumentation to facilitate the implantation of the implants. The system is comprised of instruments and perforated instrument cases that are generally comprised of aluminum, stainless steel, and/or polymeric materials.

The Ardis Inserter that is the subject of this premarket notification is an instrument intended for use with the Ardis® Interbody System. The instrument is designed specifically to implant the PEEK interbody device into a prepared disc space. The inserter threads into the posterior hole of the PEEK implant securing the implant in place with a secondary locking (anti-rotation) mechanism. The inserter design is specific to the width measurement of the PEEK implant. A 9mm width implant will be used in conjunction with the PEEK Ardis Inserter, 9mm, and an 11mm implant will be inserted using the PEEK Ardis Inserter, 11mm.

Indications for Use:
The Ardis Interbody System is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment.

The Ardis Interbody System is implanted using a posterior or transforaminal approach and is intended to be used singly or in pairs with supplemental fixation.

Device Technological Characteristics and Comparison to Predicate Device(s):
Zimmer Spine has submitted documentation demonstrating the substantial equivalence between subject and predicate devices. The unmodified versions of the instrument and the proposed version have the same intended use, operate on the same technological principles, are biocompatible for the expected patient contact profile and are cleaned and sterilized in the same way with the same parameters. The unmodified and modified versions of the Ardis® Interbody System differ only in design and materials.

Performance Date:
Design Verification Testing and Design Validation studies conducted on the Ardis Interbody System implants and instruments demonstrated the performance of the subject device was substantially equivalent in design, function, material, biocompatibility and sterilization when compared to the predicate device.

Substantial Equivalence:
Zimmer Spine Inc. has submitted documentation demonstrating the substantial equivalence of the modified and unmodified versions of the Ardis® Interbody System. The proposed Inserter instrument is similar to the unmodified version of the instrument in general form, sterilization and cleaning, and intended use. As demonstrated by supporting tests and descriptions, this design modification does not present new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Zimmer Spine, Incorporated
% Mr. Jonathan Gilbert
Director, Regulatory Affairs
7375 Bush Lake Road
Minneapolis, Minnesota 55439

September 3, 2013

Re: K131242
Trade/Device Name: Ardis® Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Spinal intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 2, 2013
Received: August 5, 2013

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131242

Device Name: **Ardis® Interbody System**

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Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices